



**THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

Appeal No:

In re the Application of: **NAGAO, Katsuyoshi, et al.**

Group Art Unit: **3761**

Serial No.: **10/509,673**

Examiner: **WIEST, Philip R.**

Filed: **October 8, 2004**

P.T.O. Confirmation No.: 6132

For: **MULTIPLE-CHAMBER MEDICAL CONTAINER AND BAG FOR ENCLOSING
SAME**

BRIEF ON APPEAL

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Date: March 1, 2010

Sir:

This Appeal Brief is respectfully submitted under the Notice of Appeal filed on December
29, 2009.

03/02/2010 SMOHAMME 00000019 012340 10509673
01 FC:1402 540.00 DA

TABLE OF CONTENTS

<u>Heading</u>	<u>Page</u>
I. REAL PARTY IN INTEREST	3
II. RELATED APPEALS AND INTERFERENCES	4
III. STATUS OF CLAIMS	5
IV. STATUS OF AMENDMENTS	6
V. SUMMARY OF CLAIMED SUBJECT MATTER	7
Summary of claim 1	7
Summary of claim 3	10
VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL	13
VII. ARGUMENTS	14
Regarding ground of rejection A	14
Regarding ground of rejection B	23
Regarding ground of rejection C	28
Regarding ground of rejection D	30
VIII. CLAIMS APPENDIX	34
IX. EVIDENCE APPENDIX (none)	41
X. RELATED PROCEEDINGS APPENDIX (none)	42

Application Serial No.: 10/509,673
Appeal Brief

I. REAL PARTY IN INTEREST

The real party in interest is Otsuka Pharmaceutical Factory, Inc., of Naruto-shi, Japan, as evidenced by the assignment recorded on October 8, 2004, at reel 016529, frame 0915.

Application Serial No.: 10/509,673
Appeal Brief

II. RELATED APPEALS AND INTERFERENCES

Appellant is aware of no related prior or pending appeal, interference, or judicial proceeding that may be related to, directly affect, be directly affected by, or have a bearing on the Board's decision in the pending appeal.

Application Serial No.: 10/509,673
Appeal Brief

III. STATUS OF CLAIMS

Claims 1, 3 and 5-25 are pending in this application. Claims 2 and 4 have been canceled without prejudice or disclaimer during prosecution. The rejections of claims 1, 3 and 5-25 are under appeal.

Application Serial No.: 10/509,673
Appeal Brief

IV. STATUS OF AMENDMENTS

No amendment has been made subsequent to the non-final Office action dated October 1, 2009.

V. SUMMARY OF THE CLAIMED SUBJECT MATTER

Claims 1 and 3 are independent. Claims 1 and 3 are separately argued below in the grounds of rejections citing both claims. Claims 1 and 3 are summarized below clause-by-clause with reference to the text of the claim (in quotation marks), and with reference to reference characters in the drawings and page and line number in the specification, as required in 41.37(c)(1)(v). The other claims are not separately argued in grounds of rejection citing more than one claim, and are not summarized here (see 41.37(c)(1)(vii)).

“Claim 1: A multiple-chamber medical container comprising:”

The claimed device is a container for enclosing different kinds of medicaments in separate chambers, one purpose being to avoid mixing the medicaments until they are needed (see page 1, lines 15-25).

“a container body having multiple chambers for containing medicaments therein and a partitioning seal portion for separating the multiple chambers from one another,”

Container body 5 is disclosed at page 8, line 4, and multiple chambers 9, 11, along with partitioning seal portion 13, are disclosed at page 8, lines 7-11.

“a medicinal outlet portion attached to the container body for discharging the medicaments from the chambers therethrough, and”

Application Serial No.: 10/509,673
Appeal Brief

Medicinal outlet portion 7 is disclosed at page 8, line 15, and may, for example, have a rubber plug that may be pierced by a needle to discharge the contents (see page 11, lines 8-10).

“an openable additional small container formed of sheet material located within at least one of the multiple chambers and having a medicament enclosed therein;”

The openable small container 15 having a medicament is disclosed at page 8, line 12, and at page 9, lines 13-15, the specification describes how it can be formed by heat-sealing the peripheral edges of two sheet material films.

“wherein the partitioning seal portion is formed by separably bonding opposing inner wall surfaces of the container body,”

This aspect of the structure is disclosed at page 8, lines 24-27, and may be seen in the structure of partitioning seal portion 13 in Fig. 2(a), where films 5a and 5b of container body 5 are bonded to form the partitioning seal portion.

“the small container is structured to open in response to external force,”

This aspect of the structure of the small container 15 is described at page 4, lines 11-14, and page 10, lines 17-25. Specifically, the external force of pressing the first or second chamber will result in opening of the small container.

“the small container has a bonded portion bonded to the container body, and”

Bonded portion 19 is disclosed at page 10, lines 7-8, and is separate from partitioning seal portion 13, as may be seen in Fig. 2(a).

“the bonded portion comprises opposing outer surfaces of the sheet material, wherein the opposing outer surfaces are each bonded to the opposing inner wall surfaces of the chambers in the vicinity of the partitioning seal portion, and”

This structure of bonded portion 19 is described at page 10, lines 5-8, and may be seen in Fig. 2(a). The bonding of the opposing outer surfaces of the sheet material of the small container 15 to the opposing inner wall surfaces of the chambers occurs “in the **vicinity**” of the partitioning seal portion 13, and therefore, the sheet material of the small container does not extend to or into partitioning seal portion 13.

“the small container is opened in accordance with the separation of the opposing inner wall surfaces of the container body.”

This limitation of the structure of the small container 15 further limits the previous recitation that the small container is structured to open in response to external force. This recitation is described at page 10, lines 26, to page 11, line 6, and is illustrated in Figs. 2(a) and (b).

“Claim 3: A multiple-chamber medical container comprising:”

The claimed device is a container for enclosing different kinds of medicaments in separate chambers, one purpose being to avoid mixing the medicaments until they are needed (see page 1, lines 15-25).

“a container body having multiple chambers for containing medicaments therein and a partitioning seal portion for separating the multiple chambers from one another,”

Container body 5 is disclosed at page 8, line 4, and multiple chambers 9, 11, along with partitioning seal portion 13, are disclosed at page 8, lines 7-11.

“a medicinal outlet portion attached to the container body for discharging the medicaments from the chambers therethrough, and”

Medicinal outlet portion 7 is disclosed at page 8, line 15, and may, for example, have a rubber plug that may be pierced by a needle to discharge the contents (see page 11, lines 8-10).

“an openable additional small container formed of sheet material located within at least one of the multiple chambers and having a medicament enclosed therein;”

The openable small container 15 having a medicament is disclosed at page 8, line 12, and at page 9, lines 13-15, the specification describes how it can be formed by heat-sealing the peripheral edges of two sheet material films.

“wherein the partitioning seal portion is formed by separably bonding opposing inner wall surfaces of the container body”

This aspect of the structure is disclosed at page 8, lines 24-27, and may be seen in the structure of partitioning seal portion 13 in Fig. 2(a), where films 5a and 5b of container body 5 are bonded to form the partitioning seal portion.

“the small container is structured to open in response to external force,”

This aspect of the structure of the small container is described at page 4, lines 11-14, and page 10, lines 17-25. Specifically, the external force of pressing the first or second chamber will result in opening of the small container.

“the small container has a bonded portion bonded to the container body, and”

Bonded portion 19 is disclosed at page 10, lines 7-8, and is separate from partitioning seal portion 13, as may be seen in Fig. 2(a).

“the bonded portion comprises opposing outer surfaces of the sheet material, wherein the opposing outer surfaces are each bonded to the inner wall surfaces of the partitioning seal portion such that the small container is positioned partly inserted into the partitioning seal portion, and”

This structure is disclosed at page 12, lines 7-8. Differently from claim 1, the small container 15 is positioned **partly inserted into partitioning seal portion 13**. That is, the opposing outer surfaces of the sheet material forming the small container 15 terminate partly inside partitioning seal

Application Serial No.: 10/509,673
Appeal Brief

portion 13. This is an alternative to the structure recited in claim 1, where the bonded portion 19 is in the **vicinity** of partitioning seal portion 13.

“the small container is opened in accordance with the separation of the opposing inner wall surfaces of the container body.”

This limitation of the structure of the small container further limits the previous recitation that the small container is structured to open in response to external force. This recitation is described at page 10, lines 26, to page 11, line 6, and is illustrated in Figs. 2(a) and (b).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

There are four grounds of rejection as stated in the Office action dated October 1, 2009:

A. Whether claims 1, 3, 5, 6, 9-12, 14-16, 17-20 and 22-25 are anticipated under 35 U.S.C. §102(b). (Note: This ground of rejection was stated in the alternative with ground B in a single rejection in paragraph no. 1 of the Office action of October 1, 2009).

B. Whether claims 1, 3, 5, 6, 9-12, 14-16, 17-20 and 22-25 are obvious under 35 U.S.C. §103(a) over Larkin (U.S. Patent No. 4,602,910). (Note: This ground of rejection was stated in the alternative with ground A in a single rejection in paragraph no. 1 of the Office action of October 1, 2009).

C. Whether claims 7 and 8 are obvious under 35 U.S.C. 103(a) over Larkin (U.S. Patent No. 4,602,910) in view of Inoue (U.S. Patent No. 5,423,421). (Paragraph no. 5 of the Office action of October 1, 2009).

D. Whether claims 13 and 21 are obvious under 35 U.S.C. §103(a) over Larkin in view of Becker (US 6,319,243). (Paragraph no. 6 of the Office action of October 1, 2009).

VII. ARGUMENT

Regarding Ground of Rejection A: Whether claims 1, 3, 5, 6, 9-12, 14-16, 17-20 and 22-25 are anticipated under 35 U.S.C. §102(b).

Separate arguments are presented below for independent claims 1 and 3.

Summary of the rejection as stated by the Examiner (see Office action of October 1, 2009, paragraph no. 2)

The rejection cites Fig. 3 of Larkin as disclosing a container body with multiple chambers, referring to the region between sheets 15 and 18, and the region between sheets 37 and 38, and states that there is a partitioning seal separating the chambers (apparently referring to sealed area 40). The Examiner states that “the system further comprises ... an openable small container 36 having a medicament 50 ... therein positioned within the first chamber 18 (see Fig. 5).”

With regard to claim 1, the Examiner discusses Fig. 6 of the reference as disclosing a bonded portion 44 bonded to the container body, comprising opposing outer surfaces of sheet material, with the opposing outer surfaces each bonded to the opposing inner wall surfaces in the vicinity of the partitioning seal portion.

With regard to claim 3, the Examiner states that: “The small container is positioned partly inserted into the portioning [sic] seal portion and is opened in accordance with the separation of the walls (15, 18) of the container body.”

On page 4, the Examiner comments on the wording of the claims that “the partitioning seal portion is formed by separably bonding opposing inner wall surfaces of the container body,” with

Application Serial No.: 10/509,673
Appeal Brief

the Examiner considering this to be product-by-process wording. The Examiner states that this is being interpreted structurally, and that the process of making it is not limiting.

Arguments against rejection of claim 1 under Ground A.

The rejection is based on the relationship between Figs. 4 and 5 of Larkin and Figs. 2(a) and (b) of the present application, which illustrate the invention of claim 1. However, Applicant submits that there are **two major differences** in structure between Larkin's device and claim 1:

1) Larkin's device does not have any structure corresponding to the "partitioning seal portion."

2) Larkin's device has only one structure corresponding to a chamber for containing medicaments, while claim 1 requires "multiple" (i.e., at least two such) chambers.

Regarding difference (1):

The lack of a "partitioning seal portion" in Larkin may be seen with reference to the explanatory drawing below, which compares Fig. 4 of Larkin to Fig. 2(a) of the present application.

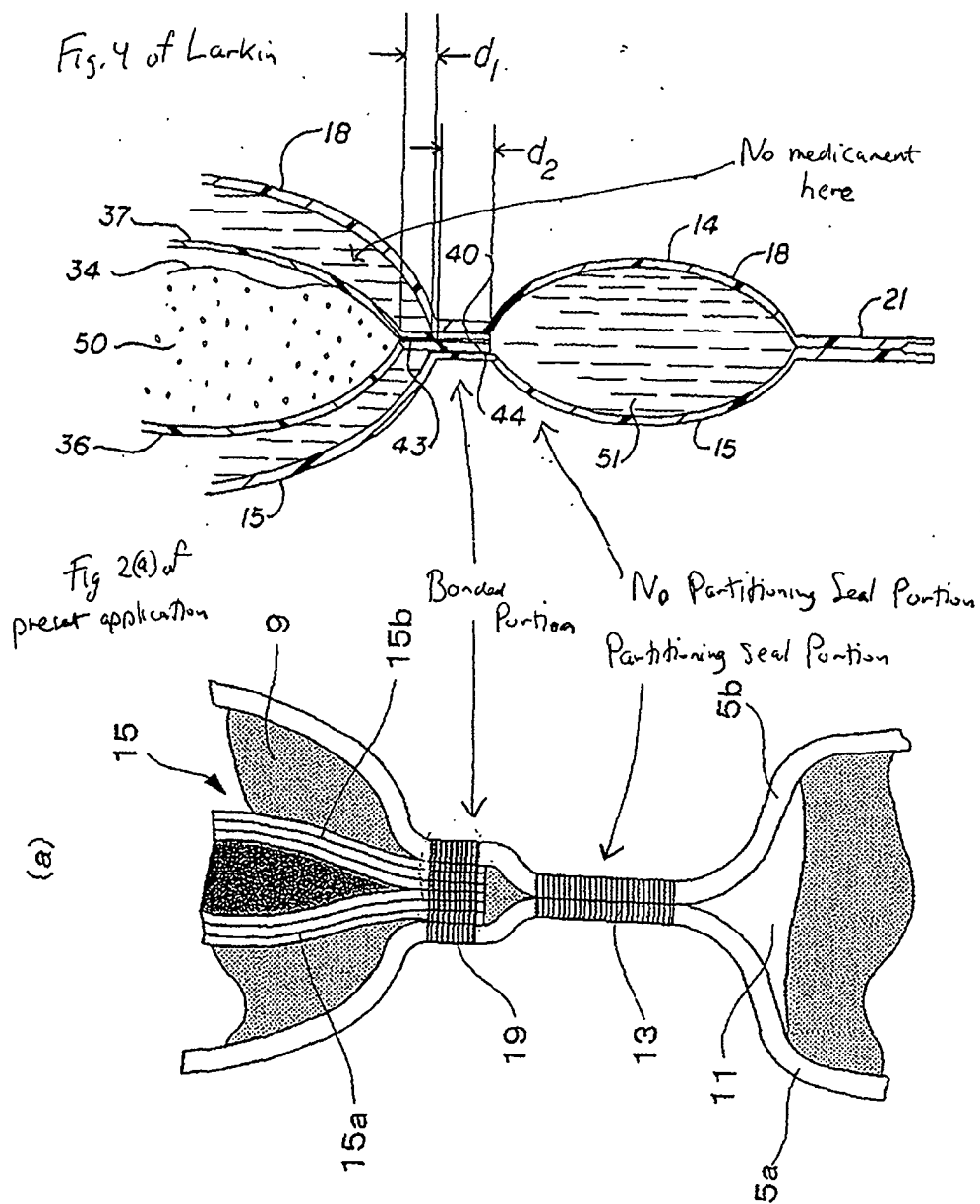
Claim 1 requires a bonded portion that comprises outer surfaces of the sheet material, wherein the opposing outer surfaces are each bonded to the opposing inner wall surfaces of the chamber. The structure of bonded portion 19 may be seen in Fig. 2(a) of the present application. As can be seen in Fig. 2(a) (and below in the explanatory drawing), this structure requires a bonding of one chamber wall, one sheet material of the small container, a second sheet material of the small container, and the other chamber wall, in that order.

As can be seen in Larkin's Fig. 4 (and below in the explanatory drawing), in Larkin's seal region 40, the walls are bonded in the order 18--37--36--15. The structure of Larkin's seal region 40 therefore corresponds in structure to bonded portion 19 as recited in claim 1.

However, claim 1 also recites a **partitioning seal portion** as an additional element. In claim 1, “the partitioning seal portion is formed by separably bonding opposing inner wall surfaces of the container body.” The partitioning seal portion 13 may be seen in Fig. 2(a) of the specification. This structure would correspond to bonding walls 15 and 18 of Larkin. However, as can be seen in Fig. 4, **there is no location (to the left of chamber 14) in Larkin where back wall 18 is bonded to front wall 15.**

That is, Larkin shows a structure corresponding to the “bonded portion,” but **no structure corresponding to the “partitioning seal portion.”** Larkin cannot anticipate claim 1.

EXPLANATORY DRAWING



Regarding difference (2):

In the rejection, the Examiner is considering the region in Larkin between sheets 18 and 37 (or the region between sheets 15 and 36; see Fig. 4) to be a chamber “capable of containing medicaments therein.”

However, in Larkin, the regions between sheet 18 and 37 and between sheets 15 and 36 are empty, and are **not** “for containing medicaments.” That these regions are **empty** and, moreover, are **not capable** of containing medicaments can be seen by reviewing the method of making Larkin’s device.

Specifically, Larkin’s device is formed from four walls 15, 18, 36 and 37. In fabrication, as described at column 3, lines 39-47, material 50 is placed between walls 36 and 37, which are sealed in seal area 43, to form second container 34. This container is then heat-sealed to walls 15 and 18 to form seal area 40, as seen in Fig. 4 (see column 3, lines 47-51). In addition, container 14 in Larkin contains a diluent (column 3, lines 53-58). Therefore, there are, in effect, two containers in Larkin containing medicaments.

As explained in Larkin at column 2, lines 9-11, and at column 3, lines 15-17, the second container (i.e., 34) is positioned within the body section 11 of primary container 14. As can be seen in Fig. 3, one medicament (50) is inside container 34, but the region between wall 37 and wall 18 and the region between wall 36 and wall 15 are **empty** (see Explanatory Drawing, above). These regions result from the sealing of the pre-filled container 34 between the walls of the primary container, but this sealing is performed without any material filling these regions.

That there is no material in these regions may also be seen Fig. 5 of Larkin, which illustrates the state when Larkin's seal 40 is broken. As described at column 4, lines 16-23, the delaminated seal 43 is a weaker seal and is designed to break prior to any breaking of the seal between the container walls. As seen in Fig. 5, the seal between walls 15 and 36 and the seal between walls 18 and 37 remain intact, and the regions between these walls do not open up to the secondary container 34 and the primary container 14 when the contents of those container are mixed. That is, the structure of Larkin's device does not include any medicament in these regions, and it does not appear that it would even be possible to place medicament in these regions.

Therefore, Larkin's device only includes one chamber for containing medicament as in claim 1 (primary container 14), while claim 1 requires as least two chambers for containing medicament.

Conclusion

Since Larkin does not disclose (1) a partitioning seal portion or (2) multiple chambers as recited in claim 1, Larkin cannot anticipate claim 1.

Arguments against rejection of claim 3 under Ground A.

Applicant submits that there are **two major differences** in structure between Larkin's device and claim 3:

1) Larkin's device does not have any structure corresponding to the "partitioning seal portion."

2) Larkin's device has only one structure corresponding to a chamber containing medicament, while claim 3 requires "multiple" (i.e., at least two such) chambers.

Regarding difference (1):

Claim 3 requires both a bonded portion and a partitioning seal portion. In claim 3, "the bonded portion comprises opposing outer surfaces of the sheet material, wherein the opposing outer surfaces are each bonded to the inner wall surfaces of the partitioning seal portion such that the small container is positioned partly inserted into the partitioning seal portion."

The recited structure therefore differs somewhat from Fig. 2(a) of the present application in that in claim 3, there is partial insertion of the small container into the partitioning seal portion. That is, the sheet material of the small container extends partly into the partitioning seal portion.

As discussed above in regard to claim 1, as can be seen in Larkin's Fig. 4 (and above in the explanatory drawing), in Larkin's seal region 40, the walls are bonded in the order 18--37--36--15. The structure of Larkin's seal region 40 therefore generally corresponds in structure to the bonding of the opposing outer surfaces to the inner wall surfaces, as recited in claim 3.

However, attention is called to location d_2 in Larkin's Fig. 4, where Larkin's walls 36 and 37 can be seen to terminate. At this location, walls 18 and 15 can be seen to diverge to form the chamber 14. There is, therefore, **no additional "partitioning seal portion"** in Larkin. The partitioning seal portion of claim 3 is "formed by separably bonding opposing inner wall surfaces of the container body." In order to meet this limitation of claim 3, **walls 18 and 15 in Larkin would have to be bonded together to the right of location d_2 in Larkin's Fig. 4**, but, in fact, the walls diverge.

Therefore, Larkin does not disclose a "partitioning seal portion" and accordingly, there is no structure corresponding to the partial insertion of the small container into the partitioning seal portion.

Regarding difference (2):

Applicant's arguments presented above in regard to claim 1 in regard to difference (2) are fully applicable to claim 3, and are not repeated here in the interest of brevity.

Conclusion

Since Larkin does not disclose (1) a partitioning seal portion or (2) multiple chambers as recited in claim 3, Larkin cannot anticipate claim 3.

Application Serial No.: 10/509,673
Appeal Brief

Regarding Ground of Rejection B. Whether claims 1, 3, 5, 6, 9-12, 14-16, 17-20 and 22-25 are obvious under 35 U.S.C. §103(a) over Larkin (U.S. Patent No. 4,602,910).

Separate arguments are presented below for independent claims 1 and 3.

Summary of the rejection as stated by the Examiner (see Office action of October 1, 2009, paragraph no. 2)

The rejection is stated in the alternative with the anticipation rejection under 35 U.S.C. 102(b) (Ground A). The obviousness portion of the rejection is not clearly distinguished from the anticipation portion.

Arguments against rejection of claim 1 under Ground B.

Applicant refers to the above arguments for the corresponding anticipation rejection of claim 1 (Ground A). In arguing against that rejection, Applicant argued that there are **two major differences** in structure between Larkin's device and claim 1:

1) Larkin's device does not have any structure corresponding to the "partitioning seal portion."

2) Larkin's device has only one structure corresponding to a chamber containing medicament, while claim 1 requires "multiple" (i.e., at least two such) chambers.

In addressing the obviousness rejection, Applicant further argues that there is no suggestion or motivation in Larkin for a modification of Larkin to have these structures. Applicant submits that none of the exemplary rationales given in the Supreme Court decision in *KSR Int'l Co. v. Teleflex, Inc.* (2007) would provide such a motivation or support a conclusion of obviousness for claim 1.

Specifically, there is no motivation to modify Larkin to have a further "partitioning seal portion" in the vicinity of the "bonded portion." As discussed above, Larkin's structure generally corresponds to the bonded portion, and as can be seen in Larkin's Figs. 4 and 5, Larkin's structure functions completely adequately for Larkin's intended purpose. Adding an additional "partitioning seal portion" in Larkin by bonding walls 15 and 18 to the right of seal 40 in Fig. 4 would not accomplish anything in Larkin. Moreover, Larkin's materials are such that the bonding between walls 15 and 18 would not form a "weaker seal," since such a seal portion would be of the same strength as the seal between container walls 21, and would not properly break (see Larkin at column 4, lines 16-22).

Moreover, there is no suggestion in Larkin that the region between walls 37 and 18, or between walls 36 and 15, be filled with a medicament (that is, no “multiple chambers” in Larkin). As can be seen in Larkin’s Fig. 5, Larkin’s device is designed to permit mixing of chamber 14 with the region between walls 36 and 37, but there is no opening of the region between walls 37 and 18, or between walls 36 and 15, upon operation of Larkin’s device.

As noted above, none of the *KSR Int’l Co. v. Teleflex, Inc.* rationales would provide a motivation for such a modification. The modifications of Larkin to meet the structure of claim 1 represent more than simply “combining prior art elements” or “simple substitution of one element for another,” and represent a structure that is distinctly different from that of Larkin.

Arguments against rejection of claim 3 under Ground B.

Applicant refers to the above arguments for the corresponding anticipation rejection of claim 3 (Ground A). In arguing against that rejection, Applicant argued that there are **two major differences** in structure between Larkin's device and claim 3:

1) Larkin's device does not have any structure corresponding to the "partitioning seal portion."

2) Larkin's device has only one structure corresponding to a chamber containing medicament, while claim 3 requires "multiple" (i.e., at least two such) chambers.

In addressing the obviousness rejection, Applicant further argues that there is no suggestion or motivation in Larkin for a modification of Larkin to have these structures. Applicant submits that none of the exemplary rationales given in the Supreme Court decision in *KSR Int'l Co. v. Teleflex, Inc.* (2007) would provide such a motivation or support a conclusion of obviousness for claim 3.

Specifically, there is no motivation to modify Larkin to have a further "partitioning seal portion" into which the small chamber is partly inserted. As discussed above, Larkin's structure generally corresponds to the "bonded portion" without the additional "partitioning seal portion," and as can be seen in Larkin's Figs. 4 and 5, Larkin's structure functions completely adequately for Larkin's intended purpose. Adding an additional "partitioning seal portion" in Larkin by bonding walls 15 and 18 immediately to the right of seal 40 (such that the small chamber was partly inserted) in Fig. 4 would not accomplish anything in Larkin. Moreover, Larkin's materials are such that the bonding between walls 15 and 18 would not form a "weaker seal," since such a seal portion would

be of the same strength as the seal between container walls 21, and would not properly break (see Larkin at column 4, lines 16-22).

Moreover, there is no suggestion in Larkin that the region between walls 37 and 18, or between walls 36 and 15, be filled with a medicament (that is, no “multiple chambers” in Larkin). As can be seen in Larkin’s Fig. 5, Larkin’s device is designed to permit mixing of chamber 14 with the region between walls 36 and 37, but there is no opening of the region between walls 37 and 18, or between walls 36 and 15, upon operation of Larkin’s device.

As noted above, none of the *KSR Int’l Co. v. Teleflex, Inc.* rationales would provide a motivation for such a modification. The modifications of Larkin to meet the structure of claim 3 represent more than simply “combining prior art elements” or “simple substitution of one element for another,” and represent a structure that is distinctly different from that of Larkin.

Application Serial No.: 10/509,673
Appeal Brief

Regarding Ground of Rejection C: Whether claims 7 and 8 are obvious under 35 U.S.C. 103(a) over Larkin (U.S. Patent No. 4,602,910) in view of Inoue (U.S. Patent No. 5,423,421).

Summary of the rejection as stated by the Examiner (see Office action of October 1, 2009, paragraph no. 5)

The Examiner states that Larkin teaches the device substantially as claimed [in base claim 1], but does not disclose that the seal [i.e, the “bonded portion”] comprises a plurality of bonded parts arranged with at least one non-bonded part therebetween. The Examiner cites Inoue as disclosing a multichamber container wherein a small container is fluidly connected to a large container by a separable bonded section. The bonded section is cited as comprising a non-bonded portion 9 in the center of the bonded portion. The Examiner states that this reduces the strength of the seal, and states that it would have been obvious to modify the device of Larkin with the unsealed portion of the bonded section of Inoue in order to improve the breakability of the seal.

Arguments against rejection of claims 7 and 8 under Ground C.

In arguing against the rejection of claim 7 and 8 over the combination of Larkin and Inoue, Applicant refers to the above arguments in Grounds A and B regarding the rejection of claim 1 over Larkin. Applicant argued that there are **two major differences** in structure between Larkin’s device and claim 1:

1) Larkin’s device does not have any structure corresponding to the “partitioning seal portion.”

2) Larkin's device has only one structure corresponding to a chamber containing medicament, while claim 1 requires "multiple" (i.e., at least two such) chambers.

Applicant has argued that there is no suggestion or motivation in Larkin to modify Larkin's device to have these structural limitations.

As discussed above, Larkin's seal 40 does correspond generally in structure to the bonded portion in claim 1. In the present rejection, Inoue is cited to provide a modification of Larkin's seal 40 (i.e., bonded portion) to have a non-bonded part positioned therebetween. However, such a modification would only change the structure of Larkin's seal portion 40, and even if Larkin were modified in this manner, the resulting structure would still not have a separate "partitioning seal portion" as required by base claim 1, and the structure would not have multiple chambers as required by claim 1.

Applicant further submits that there is no motivation in Inoue to make the major modifications in the structure in Larkin that would be necessary to meet the structural limitations of claim 1. Applicant notes, in particular, Fig. 1 of Inoue, and the seal structure in region B. In Inoue, the outer walls terminate in region B, and the inner walls forming the upper small chamber continue as the walls of the lower chamber (container body). It would therefore be impossible to form a partitioning seal portion, made by bonding inner wall surfaces of the container body, from Inoue's structure.

Claims 7 and 8 are therefore not obvious over Larkin and Inoue, taken separately or in combination.

Regarding Ground of Rejection D: Whether claims 13 and 21 are obvious under 35 U.S.C. §103(a) over Larkin in view of Becker (US 6,319,243).

Summary of the rejection as stated by the Examiner (see Office action of October 1, 2009, paragraph no. 6)

The Examiner states that Larkin teaches the device substantially as claimed [in base claims 1 and 3], but does not disclose that the small container is disposed in the same chamber as the outlet portion. The Examiner cites Becker as disclosing a multichamber container for mixing medicaments, wherein a plurality of breakable seals (18, 20) are positioned between the chambers. The Examiner cites Becker for having a plurality of outlets (31, 32, 34), one in each chamber, such that fluid may be selectively drained from any of the chambers. The Examiner states that it would have been obvious to modify Larkin's device to have Becker's plurality of fluid outlets, such that fluid could be mixed and drained in a variety of ways.

Arguments against rejection of claims 13 and 21 under Ground D.

In arguing against the rejection of claim 7 and 8 over the combination of Larkin and Inoue, Applicant refers to the above arguments in Grounds A and B regarding the rejection of claims 1 and 3 over Larkin. Applicant argued that there are **two major differences** in structure between Larkin's device and claims 1 and 3:

1) Larkin's device does not have any structure corresponding to the "partitioning seal portion."

2) Larkin's device has only one structure corresponding to a chamber containing medicament, while the claims requires "multiple" (i.e., at least two such) chambers.

Applicant has argued that there is no suggestion or motivation in Larkin to modify Larkin's device to have these structural limitations.

Applicant notes the following points about the proposed combination of Larkin with Becker.

First of all, in Becker, as seen in Figs. 1 and 2, outlets 31, 32 and 34 are at the bottom of Becker's device, where chambers 12, 14 and 16 meet the bottom edge of Becker's device. The Examiner is apparently proposing to modify Larkin's device somewhere in the vicinity of second container 34 to have an outlet.

However, second container 34 in Larkin is completely enclosed within body section 11 of primary container 14 (see Larkin, column 3, lines 15-19). There is no clear location in Larkin for an outlet for second container 34, since it is inside walls 15 and 18.

Moreover, the rejection appears to be based on the Examiner's interpretation of Larkin as having a "chamber" in the region between walls 18 and 37 or walls 15 and 36, as discussed above in regard to ground of rejection A. As discussed in regard to ground of rejection A, these regions in Larkin do not form a "chamber" and do **not** contain a medicament. There would be no motivation to attach an outlet to these regions in Larkin, since there is nothing in them to dispense.

Applicant further submits that there is no disclosure in Becker that suggests modifying Larkin to have an additional partitioning seal portion, or to have medicament in the region between walls 18 and 37 or walls 15 and 36.

Application Serial No.: 10/509,673
Appeal Brief

Claims 13 and 21 are therefore not obvious over Larkin and Becker, taken separately or in combination.

Conclusion

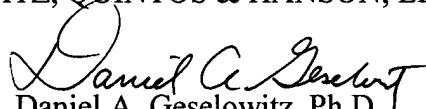
Applicant submits that no combination of Larkin, Inoue and Becker would yield a device with the limitations of the pending claims. Reversal of grounds of rejection A, B, C and D is therefore respectfully requested.

Application Serial No.: 10/509,673
Appeal Brief

In the event this paper is not timely filed, appellant hereby petitions for an appropriate extension of time. The fee for any such extension may be charged to our Deposit Account No. 01-2340, along with any other additional fees which may be required with respect to this paper.

Respectfully submitted,

KRATZ, QUINTOS & HANSON, LLP


Daniel A. Geselowitz, Ph.D.
Agent for Applicants
Reg. No. 42,573

DAG/xl

Atty. Docket No. **040520**
Suite 400
1420 K Street, N.W.
Washington, D.C. 20005
(202) 659-2930



23850

PATENT & TRADEMARK OFFICE

Appendices: VIII. Claims Appendix
IX Evidence Appendix
X. Related Proceedings Appendix

H:\040\040520\Appeal Brief

VIII. CLAIMS APPENDIX

Claim 1, 3 and 5-25 involved in the appeal. Claims 2 and 4 have been canceled without prejudice or disclaimer during prosecution.

Claim 1: A multiple-chamber medical container comprising:

a container body having multiple chambers for containing medicaments therein and a partitioning seal portion for separating the multiple chambers from one another,

a medicinal outlet portion attached to the container body for discharging the medicaments from the chambers therethrough, and

an openable additional small container formed of sheet material located within at least one of the multiple chambers and having a medicament enclosed therein;

wherein the partitioning seal portion is formed by separably bonding opposing inner wall surfaces of the container body,

the small container is structured to open in response to external force,

the small container has a bonded portion bonded to the container body, and

the bonded portion comprises opposing outer surfaces of the sheet material, wherein the opposing outer surfaces are each bonded to the opposing inner wall surfaces of the chambers in the vicinity of the partitioning seal portion, and

the small container is opened in accordance with the separation of the opposing inner wall surfaces of the container body.

Claim 3: A multiple-chamber medical container comprising:

a container body having multiple chambers for containing medicaments therein and a partitioning seal portion for separating the multiple chambers from one another,

a medicinal outlet portion attached to the container body for discharging the medicaments from the chambers therethrough, and

an openable additional small container formed of sheet material located within at least one of the multiple chambers and having a medicament enclosed therein;

wherein the partitioning seal portion is formed by separably bonding opposing inner wall surfaces of the container body

the small container is structured to open in response to external force,

the small container has a bonded portion bonded to the container body, and

the bonded portion comprises opposing outer surfaces of the sheet material, wherein the opposing outer surfaces are each bonded to the inner wall surfaces of the partitioning seal portion such that the small container is positioned partly inserted into the partitioning seal portion, and

the small container is opened in accordance with the separation of the opposing inner wall surfaces of the container body.

Claim 5: A multiple-chamber medical container according to claim 1, wherein the distance between the small container and the partitioning seal portion is 0 to 50 mm.

Claim 6: A multiple-chamber medical container according to claim 1 wherein,

the small container is heat-sealed at at least one portion of a peripheral edge thereof,
the heat-sealed portion is structured to open in response to external force,
a nonbonded portion of the small container inwardly of the sealed portion of the peripheral edge has the bonded portion bonded to the container body.

Claim 7: A multiple-chamber medical container according to claim 1, wherein the bonded portion of the small container comprises a plurality of bonded parts arranged with at least one nonbonded part positioned therebetween.

Claim 8: A multiple-chamber medical container according to claim 7, wherein said at least one nonbonded part is provided in the vicinity of the center of the bonded portion.

Claim 9: A multiple-chamber medical container according to claim 1, wherein the sheet material of the small container comprises a multilayer film and the small container is opened by delaminating the multilayer film.

Claim 10: A multiple-chamber medical container according to claim 9, wherein the sheet material of the small container comprises a multilayer film formed by laminating a plurality of resin layers having low miscibility with one another.

Application Serial No.: 10/509,673
Appeal Brief

Claim 11: A multiple-chamber medical container according to claim 1, wherein the sheet material of the small container is at least partly heat-sealed, the heat-sealed portion is structured to open in response to an external force.

Claim 12: A multiple-chamber medical container according to claim 1, wherein the small container is disposed in at least one of the chambers to thereby accommodate the medicament in the chamber.

Claim 13: A multiple-chamber medical container according to claim 12, wherein the medicinal outlet portion is connected to the chamber having the small container disposed therein.

Claim 14: A multiple-chamber medical container according to claim 1, wherein a discharge-control seal portion is further provided as an openable partition between the medicinal outlet portion and the chamber.

Claim 15: A multiple-chamber medical container according to claim 1, wherein a medicament selected from among an antibiotic, anticancer drug, cardiogenic drug, vitamin and trace element is enclosed in the small container.

Claim 16: A bag for enclosing therein at least one multiple-chamber medical container according to claim 1, wherein

the bonded portion of the small container is provided approximately in parallel to the partitioning seal portion, and

the medical container is folded along an edge of the bonded portion on one side thereof opposite to the partitioning seal portion before being placed into the bag.

Claim 17: A multiple-chamber medical container according to claim 3, wherein the sheet material of the small container comprises a multilayer film and the small container is opened by delaminating the multilayer film.

Claim 18: A multiple-chamber medical container according to claim 17, wherein the sheet material of the small container comprises a multilayer film formed by laminating a plurality of resin layers having low miscibility with one another.

Claim 19: A multiple-chamber medical container according to claim 3, wherein the sheet material of the small container is at least partly heat-sealed, the heat-sealed portion is structured to open in response to an external force.

Claim 20: A multiple-chamber medical container according to claim 3, wherein the small container is disposed in at least one of the chambers to thereby accommodate the medicament in the chamber.

Claim 21: A multiple-chamber medical container according to claim 20, wherein the medicinal outlet portion is connected to the chamber having the small container disposed therein.

Claim 22: A multiple-chamber medical container according to claim 3, wherein a discharge-control seal portion is further provided as an openable partition between the medicinal outlet portion and the chamber.

Claim 23: A multiple-chamber medical container according to claim 3, wherein a medicament selected from among an antibiotic, anticancer drug, cardiogenic drug, vitamin and trace element is enclosed in the small container.

Claim 24: A bag for enclosing therein at least one multiple-chamber medical container according to claim 3, wherein

the bonded portion of the small container is provided approximately in parallel to the partitioning seal portion, and

the medical container is folded along an edge of the bonded portion on one side thereof opposite to the partitioning seal portion before being placed into the bag.

Claim 25: A multiple-chamber medical container according to claim 1, wherein:

the sheet material of the small container is at least partly heat-sealed;

Application Serial No.: 10/509,673
Appeal Brief

the heat-sealed portion is structured to open in response to an external force; and

the bonded portion is located on the heat-sealed portion.

Application Serial No.: 10/509,673
Appeal Brief

IX. EVIDENCE APPENDIX

No evidence is attached.

Application Serial No.: 10/509,673
Appeal Brief

X. RELATED PROCEEDINGS APPENDIX

There are no related proceedings.